MAR 2 6 2009

Special 510(k) Summary of Safety and Effectiveness: Reflex Translational Anterior Cervical Plate System

Line Extension to the Stryker Spine Reflex® Hybrid ACP System

Proprietary Name:	Reflex® Translational ACP System
Common Name:	Anterior Cervical Plate System
Proposed Regulatory Class:	Class II
	Spinal Intervertebral Body Fixation Orthosis, 21 CFR 888.3060
Device Product Code:	KWQ
Sponsor:	Stryker Spine
For Information contact:	Kimberly Lane Regulatory Affairs Specialist 2 Pearl Court Allendale, NJ 07401 Telephone: (201) 760-8215 Fax: (201) 760-8415 Email: Kimberly.Lane@stryker.com
Date Summary Prepared:	October 7, 2008
Predicate Device	Stryker Spine Reflex® Hybrid ACP System (K062310, K040261) and Synthes Spine Cervical Spine Locking Plate System (K000536, K000742)
Device Description	This Special 510(k) premarket notification is intended to introduce the following line extensions to the Reflex Hybrid Plates approved under K000742 and K000536: Translational plates in 1-level, 2-level, 3-level, and 4-level

	configurations and in lengths ranging from 14mm through 96mm
Intended Use	The Stryker Spine Reflex® Translational Anterior Cervical Plating (ACP) System is intended for use as an aid in cervical spinal fusion and is intended for unilateral fixation. The Reflex® Translational Anterior Cervical Plating System is intended for anterior intervertebral screw fixation of the cervical spine at levels C2-T1. The system is indicated for temporary stabilization of the anterior spine during the development of cervical spine fusions in patients with the following indications: ▪ Degenerative Disc Disease (as defined by neck pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies) ▪ Trauma (including fractures) ▪ Tumors ▪ Deformities or curvatures (including kyphosis, lordosis, or scoliosis) ▪ Pseudarthrosis ▪ Failed previous fusion ▪ Decompression of the spinal cord following total or partial cervical vertebrectomy ▪ Spondylolisthesis ▪ Spinal stenosis WARNING: This device is not approved or intended for screw attachment or fixation to the posterior elements (pedicles) of the cervical, thoracic, or lumbar spine.
Summary of the Technological Characteristics	The intended use and materials of the subject anterior cervical plates are identical to those of the predicate anterior cervical plates. The predicate Reflex® Hybrid Anterior Cervical Plate (ACP) System consists of various size plates that are implanted and remain static. The subject system consists of various length plates that have Titanium clips which hold the plate in the "fully open" position. After the plate is placed and secured, Titanium clips are

removed allowing the plate to decrease in size up to 2mm per level treated. This translational plate design uses the same screws and locking mechanism used in the predicate Stryker Spine Reflex® Hybrid ACP System. Engineering analysis and performance testing verify that the subject device system is substantially equivalent in terms of performance characteristics to the predicate device systems.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Stryker Spine
% Ms. Kimberly Lane
Regulatory Affairs Specialist
2 Pearl Court
Allendale, New Jersey 07401

MAR 2 6 2009

Re: K083020
Trade/Device Name: Stryker Spine Reflex® Translational Anterior Cervical Plating System
Regulation Number: 21 CFR 888.3060
Regulation Name: Spinal intervertebral body fixation orthosis
Regulatory Class: II
Product Code: KWQ
Dated: February 23, 2009
Received: February 24, 2009

Dear Ms. Lane:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at toll-free number (800) 638-2041 or (240) 276-3150 or the Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K 083020

Device Name: Stryker Spine Reflex® Translational Anterior Cervical Plating System

Indications For Use:

The Stryker Spine Reflex® Translational Cervical Plating (ACP) System is intended for use as an aid in cervical spinal fusion and is intended for unilateral fixation.

The Reflex® Translational Anterior Cervical Plating System is intended for anterior intervertebral screw fixation of the cervical spine at levels C2-T1. The system is indicated for temporary stabilization of the anterior spine during the development of cervical spine fusions in patients with the following indications:

- Degenerative Disc Disease (as defined by neck pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies)
- Trauma (including fractures)
- Tumors
- Deformities or curvatures (including kyphosis, lordosis, or scoliosis)
- Pseudarthrosis
- Failed previous fusion
- Decompression of the spinal cord following total or partial cervical vertebrectomy
- Spondylolisthesis
- Spinal stenosis

WARNING: This device is not approved or intended for screw attachment or fixation to the posterior elements (pedicles) of the cervical, thoracic, or lumbar spine.

Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative,
and Neurological Devices page 1 of 1

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